

Questions and Answers on 10 CFR 830 Implementation

Answers provided by EH-53

<u>Site/Office</u>	<u>Rule Section</u>	<u>Question</u>	<u>Answer</u>
Carlsbad		1. Do we need to do anything in addition to the annual revision of the SAR?	Following DOE approval of the safety basis documents and the USQ procedure, contractors must continue to operate their nuclear facilities in accordance with the safety basis and to meet the USQ process. In addition, they must annually submit an updated safety basis or a letter confirming that there have been no changes to the safety basis in the last year. They must also submit a USQ summary annually. Contractors who are already providing annual updates may continue to provide these updates on the existing annual schedules, provided they meet the schedules in the rule.
Carlsbad		2. Question has to do with commercially procured components that are dedicated for nuclear service. If a system is in service that may not have a formal dedication for nuclear service, do we need to go back and address these types of situations or are they grandfathered?	The DOE-approved DSA and TSR should define the requirements for these components. Safety structures, systems & components (SSCs) should be shown to be capable of performing their intended function. If this cannot be shown, compensatory measures should be identified. If there are no compensatory measures possible, DOE has the option of accepting the risk or requiring the modification.
Carlsbad		3. How does DOE document approval of a PDSA?	3. PDSA approval should be documented in writing with an SER approved by the person authorized in the FRAM .
Carlsbad	10 CFR 830.205(b)	4. In 10 CFR 830.205(b) for TSRs, what specifically does “a person in authority as designated in the Technical Safety Requirements” require? Names or positions?	4. To avoid needless DOE approvals of changes when personnel change, it is advisable to designate positions, rather than names.
Carlsbad		5. In Appendix A, Section G, Hazard Controls, Number 5, does the “authorized users list” have to be formalized in a procedure? We have a distribution list by location only and it is an informal list discussed with DOE.	5. The authorized user list should be formalized. A procedure for keeping the list current and for distributing updates to the documents would be appropriate.
Carlsbad		6. DNFSB Recommendation 2000-2 broadened the definition of “safety systems” beyond that of DOE-STD-	6. Vital safety systems, per the 2000-2 Implementation Plan, may extend beyond SC and SS SSCs. A 2000-2 meeting in Livermore, CA addressed this issue. The resolution was that

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		3009. However, we believe “important to safety” as defined by 10 CFR 830, only applies to safety class and safety significant SSCs as defined by the PDSA or DSA. Additionally, “vital” safety systems may still need to be managed with greater importance than “balance of facility” equipment. How do we handle vital systems that are not safety systems?	vital safety systems should include SC and SS SSCs, plus consideration of a short list of designated SSCs, plus any other SSCs that line management designates. The 2000-2 Implementation Plan also addresses additional measures for vital safety systems, such as configuration management and designation of System Engineers. See, also, the USQ requirements regarding items important to safety. These extend beyond SC and SS SSCs.
Carlsbad		7. Major modifications are defined in the Rule as “a modification to a DOE nuclear facility that is completed on or after 4/9/01 <i>that substantially changes the existing safety basis for the facility.</i> ” What should be used as criteria for determining a “substantial change”? Would any change that could result in a positive USQ be a “substantial change”?	7. This decision must be made on a case-by-case basis between the DOE line organizations and the contractor. No, a change resulting in a positive USQD is not necessarily a major modification.
Carlsbad		8. We have a project that has an existing SAR with proposed changes. Last summer, a USQ with hazard and accident analysis and SAR text revisions was approved by the contractor, prior to DOE approval of the USQ changes were made to the analyzed process. Construction is just starting and will not be complete by 4/9/01. Do we need to prepare a PDSA, or will the existing analysis suffice?	8. The question is unclear. It appear that the contractor approved a SAR and prepared a USQD and a safety analysis for a proposed change. Then construction was started without any DOE approvals. If this is the case, then the contractor is in violation of DOE Orders 5480.23 and 5480.21. The rule requires a PDSA for a major modification or a new facility if construction begins after 12/11/2000 and operation begins after 4/9/2001.
Carlsbad		9. We have another project with a PSAR that has been submitted to DOE, construction started before 12/10/00 and	Provided the existing PSAR meets the rule requirements for a PDSA, it should be sufficient to update the PSAR to reflect the modification to the activity and submit it to DOE for approval.

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		will not be completed by 4/9/01. We are now adding an additional process for which construction did not start prior to 12/10/00 and will not be completed by 4/9/01. We have a hazard analysis and are currently developing an accident analysis. Do we need to submit a PDSA, or will updating the existing PSAR suffice?	
Carlsbad		10. In DOE G 423.X, Implementation Guide for Use in Developing Technical Safety Requirements, Section IV.15, it states for safety significant SSCs that TSR "coverage would likely be through an LCO or AC." What are the criteria for determining when we need LCOs vs. ACs?	Judgment of safety professionals and approval by DOE.
Carlsbad		11. In DOE G 424.X-X, Implementation Guide for Use in Addressing Unreviewed Safety Question (USQ) Requirements, Section III.B, it states, "Changes for which management has already decided will be submitted to DOE for safety review and approval" can be screened; therefore, not requiring the performance of a USQD. What is the intent of this statement?	If it has already been determined that an action requires DOE approval, it is not necessary to invoke the USQ process. This is because the purpose of the USQ process is only to determine when DOE approval for an action is required, not for approval of the action.
Idaho		1. What is the approval process? Do you have to write an SER for a previously existing 5480.23 SAR?	1. If you have an existing 5480.23 SAR that meets the requirements of the rule, you need only re-affirm those in accordance with 830.207(c). The contractor must notify DOE that the existing SAR meets the requirements of the rule and request DOE to reaffirm their approval under the rule. If there is an existing SER for that SAR, DOE may reaffirm their

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			existing SER when approving the SAR under the rule.
Idaho		2. What is the significance of DOE approval of the USQ procedure as it relates to future enforcement actions? To independent review? Potential “enforcement bind”?	2. Each enforcement action is determined on the facts of the situation. In particular, contractors must meet their DOE-approved USQ procedures and a failure to meet the DOE-approved USQ procedure would be a noncompliance. Whether the noncompliance will result in an enforcement action will be determined on a case-by-case basis. Individual, minor noncompliances with minimal or no safety significance are unlikely to trigger consideration for enforcement unless they are related to additional noncompliances that indicate a programmatic breakdown. Other factors such as self reporting and prompt corrective action may also be considered as mitigating factors. DNFSB oversight is independent of DOE approval of the USQ procedure. However, should a DOE oversight organization disagree with the DOE-approved USQ procedure, they must direct the disagreement to the line organization that approved the procedure.
Idaho		3. With regard to the April 9 2001 deliverable, what are the true requirements of the Rule? For example, we have facilities that have SARs written after 5480.23 but prior to DOE-STD-3009. [Cites different format, with complete content.] We have SARs that are in compliance with the Order but not the Standard. What is the checklist we use to say that we are in compliance with the Rule?	3. The requirements are plain, if the methodology used to develop the safety basis complies with one of the safe harbors (for the circumstances permitted) then a contractor does not need DOE approval of the method used. If an alternate method is used, or there are deviations from the safe harbor method, then DOE approval of the method is required. However, if a contractor believes that the <u>current</u> safety basis meets the requirements of the rule (Subpart B) but not the safe harbor requirements, it should submit the safety basis to DOE by April 10, 2001 and request DOE to approve the alternate methodology when it approves the safety basis.
Idaho		4. With regard to a safe harbor for transportation activities: Will TSR’s still be required even though a transportation safety document is used to satisfy the requirements of the DSA?	4. Contractors must develop hazard controls consistent with the provisions of 10 CFR 830.205 and the hazards of the activity.

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Idaho (DOE Re-Phrase)		5. If you have the controls and they pretty much meet what you are looking for in TSRs, then can we put them in a document we are using to meet DOE orders on transportation? Are we talking about the loading dock or the packages?	5. You may use an existing format to document your hazard controls provided you meet the requirements of the rule. All aspects of a nuclear activity must be addressed, including those on the loading dock and those involving transportation packaging, as well as the transportation activity itself.
Idaho		6. In Table 2 in Appendix A, two or more alternatives for a safe harbor for DSA are listed with a connective word “or”. In the case for the safe harbor for transportation activities, the word “and” is used, and it appears to say that a safety analysis report for packaging <i>and</i> a transportation safety document would be required to constitute a DSA. Was the word “and” intentional, or may we interpret that to be “or” as well? Practice is to write a SAR for packaging only when shipping a package offsite, and a transportation safety document is prepared for transportation activities that are totally onsite activities.	6. When the rule uses “AND,” as it does for the transportation safe harbors, both criteria must be met to use the safe harbor.
Oak Ridge	10 CFR 830.207, para. B	1. If by 4/9 or 4/10 (2001), we discover that we have safety documents that do not meet the intent of the Rule, will we have to put something in place in the interim until we can upgrade them, such as a Justification for Continued Operations?	1. Per 830.207(b) you must continue to perform work in accordance with the existing safety basis pending approval of a safety basis that meets the rule. If your current safety basis does not reflect your current operations and you are not able to work to that safety basis, you must contact DOE and work to get a DOE approved safety basis that you can meet in the interim. (See the response to Comment U on page 60302 of the October 10, 2000 Interim Final Rule)
Oak Ridge		2. Does the Rule apply to Category [1,] 2 & 3 “facilities” or to transporting [1,] 2 & 3 “quantities”?	2. See the definitions for “nuclear facility and “nonreactor nuclear facility” in § 830.3 of the rule. When we use the term “nuclear facility” we mean facilities, activities and operations.

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			The term is broadly used and includes the facility and the transportation activity. (See p. 60296, par. 2.i, in the October 10, 2001, Interim Final Rule.)
Oak Ridge		3. Questions funding based on Work Smart standards.	3. Funding issues are line issues and must be directed to the line. Regardless of any positions taken in the Work Smart Standards process, contractors must meet the rule requirements. The requirement to meet the rule is fully consistent with the Necessary and Sufficient process approved for Work Smart Standards and Safety Management System requirements. (See also the response to RR on page 1816 of the Jan. 10, 2001 Final Rule)
Oakland	10 CFR 830.3	1. With regard to the definition of an “existing DOE facility,” we expect to receive the SAR for DWTF at LLNL next month. Is it considered to be a “new facility”?	1. The definition of a “new facility” is contained in § 830.3 of the rule and states that a new facility is one that begins operation on or after April 9, 2001.
Oakland	10 CFR 830.120	2. What is the lower threshold of a “nuclear facility”? (Or, what is the lower threshold of a nuclear hazard?) Is a bio-med facility using some radio-tracers a nuclear facility?	2. The Department has not defined a “lower threshold” for a nuclear facility. See the response to comment 9 on page 15844 of the preamble to the April 5, 1994 publication of Part 830 (59 FR 15843). Also see the response to question 1 in Ruling 1995-1 published Feb, 5, 1996 (61 FR 4209). The safety basis requirements of Subpart B, however, are limited to hazard category 1, 2, or 3 nuclear facilities as defined by DOE-STD-1027.
Oakland	10 CFR 830.120	3. Is there a prescribed safety basis for less than Category 3 nuclear facilities? Do we continue to use EM-STD-5502 until further notice?	3. The rule does not require safety bases for below hazard category 3 nuclear facilities. However, contract or other line direction may require safety bases for below hazard category 3 nuclear facilities. Another standard that might be considered for these facilities would be DOE-STD-1120, if appropriate.
Oakland	10 CFR 830.202	4. Section (b)(3) requires contractors to categorize facilities consistent with Standard 1027. Standard 1027, page 5, allows for the use of alternate ARFs to set Category 2/3 threshold quantities	4. Contractors may only use alternate release fractions (ARFs) for the final hazard categorization. ARFs must be approved by DOE and be based on sufficient analyses to justify alternative values. The analyses must be documented and submitted to DOE for approval. They must consider the specific waste

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		(various interpretations have covered demoting facilities to Category 3 and to Radiological). Specifically, the common ARF adjustment for “WIPP-ready” drums has been a factor of 10 (ID, OR, OAK, RF). Confirm that EM/EH continue to support category adjustments at drum storage facilities.	forms, the drums, and the accident scenarios that may be involved.
Oakland	10 CFR 830.202	5. Section (c)(2) requires the annual submittal to DOE of either the updated documented safety analysis for approval or a letter stating that there have been no changes in the documented safety analysis since the prior submission. Confirm that PDSAs do not require annual updates (or USQs). We believe that the terms for such updates should be determined and approved as part of the PDSA’s SER.	5. The rule does not require the contractor to annually update the PDSA or to apply the USQ process to the PDSA. Contract requirements, however may define update requirements and change controls for the PDSA. Furthermore, mission changes or redesigns during the design phase may necessitate updates to the PDSA. The implementation guide for the DSA includes guidance on updating the PDSA. Order 420.1, section 4.1 Implementation Guide also provides guidance on timing of submittals.
Oakland	10 CFR 830.202	6. Updates and New Facilities: DOE will approve operations at new facilities by the ORR, which may conclude nine months after the DSA is approved. When is an annual update to a facility’s first DSA due? Is the answer that that update is due “12-minus-2” months after the SER date, but a smart Lab will send DOE a letter asserting no changes at that “9-minus-1” month mark?	6. The contractor must have a DOE-approved DSA before operation of a new facility and it must operate the facility in accordance with the DOE-approved DSA. Between the approval of a DSA and an annual update, the contractor must address any changes through a DOE-approved USQ process. Therefore, if there is a lag time between the approval of the DSA and the start of operation of a facility, the contractor must address any changes to the DSA through a DOE-approved USQ process. The contractor must update the DSA at least annually. The clock starts when the last DSA (or letter stating there have been no changes) was submitted.
Oakland	10 CFR 830.204 (b)(6)	7. Confirm that Cat. 3 facilities may hold more than 450 grams of Pu, if the inherent processes and physical forms make inadvertent criticality not	7. The facility would need to be categorized as a hazard category 2 nuclear facility. Hazard controls would need to be identified accordingly. Alternatively, if segmentation or nature of process precludes potential for criticality, and this is

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		credible. Standard 1027 states criticality potential is an entry condition for Cat. 2 (pp. A3 & A12). Standard 3009, Chapter 6 (p. 75), says that Cat. 3 facilities have no credible criticality potential and may omit this section. EH's 5/00 interpretation in this matter dealt only with Cat. 2 facilities. We believe that what Cat. 3 facilities really need is a commitment to keeping criticality not credible, a description of the basic processes and forms that make it certain, and a commitment to a program to establish criticality controls and oversight.	demonstrated in final categorization, then the higher threshold quantities of Table A-1 of Attachment 1 of Standard 1027 may be used. See the footnote with three stars at the end of the table in Standard 1027.
Oakland	10 CFR 830.206 (b)(2)	8. Section (b)(2) says that DOE-approved PDSA's are required before procuring materials or components or before beginning construction. DOE may authorize the contractor to perform limited procurement and construction activities without approval of a preliminary documented safety analysis if DOE determines that the activities are not detrimental to public health and safety and are in the best interest of DOE. Does advanced (Title II) design work require a PDSA or waiver from same? For simple projects, it may be cost-effective to do a Title II design up front, and that design information (while not <i>final</i>) would be the basis of the PDSA.	8. As stated the PDSA is required by the rule before procurement or construction. The rule does not require a PDSA before design. In fact, some design effort is necessary in order to develop a PDSA.
Oakland	10 CFR 830.206	9. Confirm that PDSAs must also	9. PDSAs must meet the provisions of 830.206 and the

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		satisfy the requirements in 10 CFR 830.204(b) and follow Standard 3009, if only using a graded approach.	definition of a PDSA as stated in 830.3. They are not required to meet the requirements of 830.204, which is for DSAs. PDSAs are not required to meet DOE-STD-3009. However, because a DSA must be in place prior to operation, it makes sense to develop a PDSA according to the DSA guidance and evolve it to a DSA as design matures and construction begins.
Oakland	10 CFR 830.207	10. Is there a stigma in going from a 5480.23 SAR to a BIO? If a facility's (with a limited life) SAR arguably needs improvement, is there a disgrace with calling it a BIO to finish its days?	10. A BIO is a documented safety analysis prepared in accordance with DOE-STD-3011. Appendix A to Subpart B of 10 CFR Part 830 defines the circumstances under which DOE-STD-3011 may be used as a safe harbor method to develop the DSA. Contractors should consult the DOE line organizations if they have questions about whether a BIO is appropriate to meet the requirement for a DSA. Any deficiencies in the safety basis need to be addressed.
OH-Mound		1. West Valley has a Site SAR for onsite transportation and Mound has a BIO. Neither of these two methods are listed under safe harbor. How should we approach this?	1. Contrary to the statement, the safe harbor methods do include a SAR method (DOE-STD-3009) which can be used for all nonreactor nuclear facilities and a BIO method (DOE-STD-3011) which can be used under the circumstances prescribed in Table 2 to Appendix A of Part 830. In addition, there are 2 safe harbors specifically listed for transportation activities that may also be used. If none of the safe harbor methods listed in Table 2 are met, then the analysis should be revised or the contractor must get DOE approval of the method used.
OH-Mound		2. So, the key thing here is that there is no requirement that a contractor must use one of those safe harbor methodologies. They can use an alternative methodology as long as it is approved on the appropriate level.	2. Yes. Contractors do not have to use a safe harbor method. However, the burden of proof of an alternative method is the responsibility of the contractor and the contractor must obtain DOE approval for its use. The authority for approving an alternate methodology will be defined in the FRAM.
OH-Mound		3. Do we need to make some kind of approval submittal?	3. The rule has a number of submittal requirements, among them are requirements for submitting a safety basis (DSA & TSRs), PDSA (where required), QAPs, USQ procedures, and alternate methodologies when safe harbors are not used.

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OH-Mound		4. Re: 4/10/01 deadline, is it okay to maintain our routine cycle of annual updates for our safety basis documents for all 3 Ohio sites, and confirm that we are okay in light of the Order at that time?	<p>4. The April 9, 2001 submittal date is not an annual update requirement, but it only applies under the circumstances of 830.207(c). If the circumstances of 830.207(c) do not apply for an existing facility, then the contractor must meet the schedule requirements of 830.207(a) (April 10, 2003). The April 10, 2001 submittal date in the rule applies to the USQ procedure. The contractor must meet that date (or have an approved exemption) or be in noncompliance with the rule.</p> <p>The clock starts for the annual update of the DSA from the last date the DSA was submitted for approval or the contractor submitted a letter indicating that there have been no changes since the last submittal. If the contractor chooses to submit the update at an earlier date to maintain its current schedule and the line organization agrees, there is no reason why that cannot be done. However, if the contractor wants to extend a schedule in the rule, an exemption will be required per 10 CFR 820, Subpart E.</p>
OH-Mound		5. Is 5502 still an acceptable method to do hazard categorization?	5. No. The rule requires the hazard categorization to be done in accordance with DOE-STD-1027 (See 10 CFR 830.202(b)(3)).
OH-Mound		6. What happens when you get less than Cat. 3?	6. The contractor has the burden of proof to demonstrate that a nuclear facility is below hazard category 3, therefore the contractor should keep the records that demonstrate that determination. Contractors are not required to meet the safety basis requirements for below hazard category 3 nuclear facilities. However the QA requirements apply to all DOE nuclear facilities, including those below hazard category 3.
OH-Mound		<p>7. As far as hazard categorization documentation, only above level 3 will go to the Field Office. Anything radiological, etc., will those remain with the local office?</p> <p>Once we get below Cat. 3, to make a</p>	<p>7. The FRAM will define responsibilities and authorities, as well as whether these authorities can be delegated.</p> <p>See the discussion of nonreactor nuclear facility in the 1994 rule and the discussion of radiation in Part 835 .</p>

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		distinction between “radiological” and “other industrial”, there is no change in that process?	
OH-WV		<p>1. Since we believe that we are in compliance, all we need to do by the 4/10/01 date is reaffirm that the SERs are correct and the SARs are correct? Do we have to re-issue SERs for those SARs that have been submitted?</p> <p>So, we do not need to get out of our cycles for doing annual updates? Just make a declaration that it has been reviewed and is consistent with the Rule?</p>	<p>1. The contractor must affirm that the current safety basis meets the rule requirements and request DOE to approve it under the rule by April 9, 2001. DOE has until October 10, 2001 to reaffirm the SER or issue a new one. If DOE does not reaffirm the SER or issue a new one, then the contractor must assume that it must work with DOE to provide a new safety basis by April 10, 2003.</p> <p>The contractor does not need to change the schedule for the annual update, provided the submittals are provided in accordance with the rule schedules and the annual update are provided within a year of the last submittal to DOE.</p>
OH-WV		2. Will we still be doing the hardcopy annual safety documentation reports, giving information on our safety document information, once the EH webpage mentioned at the end of the Rule and PBX files are set up?	2. No. EM will set up a platform that can be used consistently across the Complex to get information from the sites, from contractors to the Field Offices back up to HQ as to the status of the DOE safety basis documents. It will be designed to find information and share it and promote consistency. That information will be provided to EH to support the web page.
OH-WV		3. Does every revision to the USQ determination procedure require Ohio Field Office approval?	2. Yes, but detailed information that will be subject to frequent change can be located in lower tiered documents so the USQ procedure will not be subject to frequent changes.
OH-WV		4. In the Rule, it refers to 1027-92 Change 1. It does not refer to subsequent revisions. Will that be corrected?	4. Sec. 830.202(b)(3) requires DOE STD 1027-92 to be used. If a later revision is issued for use, DOE will need to notice any desired change to the requirement in a Federal Register Notice.
OH-WV		5. Where will we look for the definition of operations for disposition activities?	5. When you begin performing disposition activities at the site you have begun disposition operations. Also see DOE-STD-1120.
OH-WV		6. When is the disposition activity being	6. The Rule requires a safety basis for any type of operations.

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		<i>operated?</i> For example, when somebody starts to do characterization? When they start to cut things? When they botch it and take it out of the cell?	When you change the type of operations you are performing at a facility, site, or activity, you will need to have a DOE-approved safety basis that reflects that new mode of operation.
Richland	10 CFR 830.207 (c)	1. Re: 207 (c), is there an expectation as to what “documenting the adequacy of the safety basis” means?	1. Document your basis for determining that the analysis meets the rule (including all the requirements in the rule), ensures that adequate protection is provided, and is consistent with current operations. See also the language in 830.4(c).
Richland		2. Provision for major modification: date was changed for the requirement for a PDSA so that it adds a provision for construction after 12/11(?), but there is no expansion on what is intended. When a PSAR or PDSA is required for a major modification, it is driven out of the Project Management organization or project requirements because it is a project-supporting document. Seems to focus on getting DOE approval on nuclear safety criteria that applies to equipment or safety systems and ensures that that gets in place before procurement and construction. [Want to tailor application of definition.] Is it strictly an agreement between the contractor and Field Office, or do we need to get something more formal or will someone come looking for a PDSA when one is not performed? DOE Re-word: When do we have to do a PDSA, or simply make a request to the DOE for a modification under the USQ process?	2. See the response to comment V on page 1814 of the Federal Register notice for the Jan. 10, 2001 Final Rule. If there are any questions regarding what constitutes a major modification (v.s. a USQ), the contractor should contact DOE to discuss it on a case-by-case basis.
Richland		3. Is deferral of the categorization of	3. Either categorize the facility and determine if a safety basis

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		[inactive] sites on the Hanford site consistent or inconsistent with the Rule?	needs to be submitted under the rule or apply for an exemption under the provisions of 10 CFR 820, Subpart E..
Richland		4. For similar activities performed at different facilities, does a PDSA have to be prepared for each?	4. It depends. If the modification is generic and the facilities are similar, with similar hazards, then a case could be made that one PDSA could apply to the multiple facilities. However, the case must be made. If it is made successfully, then the PDSA could apply to each.
Richland		5. Requests elaboration on the fact that a “graded approach” is not allowed in the USQ process.	5. The USQ requirements apply to the safety basis without grading. They define the situations when DOE approval for changes in the safety basis is required. Any grading appropriate to safety has already been applied through the development of the DSA, which is graded.
Richland		6. What does “other controls necessary to provide adequate protection from hazards” within the definition for “hazard controls” refer to?	6. The documented safety analysis will allow you, for instance, to create a HASP to satisfy TSR and USQ requirements. The hazardous requirements that come out of a HASP are not necessarily TSRs, so we needed a more expansive definition of hazard controls.
Richland		7. New Construction: With regard to PDSA, there is limited relief available for procurement. Contract provides for limited construction authorization for site excavation, etc. What is the mechanism for this limited relief?	7. Field Office has authority to give limited relief, however DOE must document the basis for the determination that the provisions of 830.206(b)(2) have been met with respect to the waiver. The implementation guide for the DSA will provide additional information.
Richland		8. Construction enforcement: Is there any intent to make the PDSA enforceable under PAAA?	8. The PDSA and the requirement for the PDSA are enforceable under the rule.
Richland		9. Are annual updates to the PDSA required, and does the USQ section apply to facilities under construction?	9. The rule does not require the contractor to annually update the PDSA or to apply the USQ process to the PDSA. However, the PDSA should be kept current to reflect the design, and therefore, periodic updating may be required.
Richland		10. Waste Treatment Project: PDSA expected 9/10. Alternative method to safe harbor methodology proposed. What is the review loop for this	10. To be discussed later with EH.

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		alternative method and the timing of that loop?	
Rocky Flats		1. What does “limited operational life” mean, other than what is in the Rule?	1. This term is further defined in the guides.
Rocky Flats		2. We may be doing deactivation in one part of a facility and decommissioning in another, or deactivation or decommissioning in one part and operations in another. What part of the Rule would we come under?	2. DOE-1120 provides guidance on this situation. Provided the facility contains sufficient material to be categorized as hazard category 1, 2, or 3, the safety basis requirements apply and the safety basis should address the activities being performed and the associated hazards. Several DSAs may also be required if the activity is segmented.
Savannah River		1. Is it correct to assume that any USQ determination must be included in the annual summary?	1. Yes.
Savannah River		2. In the transportation arena, when you follow the processes of 460.1A and the Manual, and are very specific to onsite transportation, DOE typically approves a transportation safety document (TSD) which is really the methodology used for safety evaluations. But, typically, the onsite safety evaluation for any given package is not approved by DOE. That is in line with the safe harbor. Does this conflict with the other elements in the Rule that requires DOE approval of the analysis? ... DOE Re-Phrase: Transportation safety document is a generic document covering transportation activities in general onsite. Does the rule require a TSD or safety basis for each shipment or each type of shipment?	3. The TSD can provide an analysis for specific types of transportation activities to be performed or a generic document can be approved which covers multiple transportation activities. DOE approval of the safety basis is expected, but this can be accomplished in a number of ways. More specifics may be needed to address properly. However, 460.1A requires more than just the methodology to be applied for transportation safety. It requires safety analyses. Therefore, it would be expected that generic types of transportation, at least, would be covered in a TSD. Further, the requirements for safety controls must be met.
Savannah River		3. How might the graded approach apply to the USQ process?	3. The USQ requirements apply to the safety basis without grading. They define the situations when DOE approval for

Questions and Answers on 10 CFR 830 Implementation

Answers provided by EH-53

<u>Site/Office</u>	<u>Rule Section</u>	<u>Question</u>	<u>Answer</u>
			changes in the safety basis is required. Any grading appropriate to safety has already been applied through the development of the DSA, which is graded.
Savannah River		4. Notes that alternate methodologies require the concurrence of EH; however, 1/10 memo says alternate methodologies may be approved by the Field Manager with the EM Site Office Director's concurrence. Is this the intent of the DOE?	4. When package is sent for Director's concurrence, EM will ensure that the package will be forwarded on to EH in accordance with the requirements in the FRAM. EH concurrence will be required.